Pneumothorax: Conservative or interventional treatment

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SUMMARY

This study was an open-label, multicentre randomized trial comparing two different management approaches in primary spontaneous pneumothorax (PSP). The first approach was conservative, i.e. watchful observation, and the other was interventional, i.e. insertion of a small-bore intercostal drain. Eligible patients were recruited from

39 centres in Australia and New Zealand, who belonged to the age group of 14–50 years and had a first episode of unilateral, moderate to large PSP measuring 32% or more on chest X-ray (as determined by the Collin's method).

Patients in the intervention group had small-bore (<12 French) intercostal drain inserted by the Seldinger technique. If the chest X-ray taken after an hour revealed a completely expanded lung, the drain was clamped and another chest X-ray was done after 4 hours; if it showed similar findings, the drain was removed. If, however, the pneumothorax persisted, the drain was unclamped and the patient remained hospitalized.

In the conservative approach, a chest X-ray was obtained after 4 hours of observation, and if the patient was clinically stable, he/she was discharged with instructions to return in case of any emergency.

All patients were followed up at 24–72 hours, and 2, 4 and 8 weeks with clinical and radiological investigations to detect complete re-expansion or recurrence of pneumothorax.

This was a non-inferiority trial where the sample size was calculated with a non-inferiority margin of –9%, which was an arbitrary assumption based on a consensus agreement between the clinicians and patients expecting a 90% success rate in complete resolution of pneumothorax in the conservative approach group vis-à-vis 99% in the intervention group. This was primarily due to the lack of adequate trials addressing this comparison. Based on this assumption and accounting for a 20% drop-out rate, a total of 316 patients were recruited (154 patients to the intervention group and 162 to the conservative management group).

The primary objective of the study was to determine whether the conservative approach was non-inferior to the interventional approach for complete resolution of the pneumothorax within 8 weeks. If the follow-up data were not available in 8 weeks, it was reported as missing. A sensitivity analysis was also reported where the 8-week follow-up visit was extended to 63 days for assessment of the results.

Of the total number of patients, 23 patients in the intervention group and 37 in the conservative group did not have the necessary data, and among the remaining, re-expansion of pneumothorax within 8 weeks occurred in 129/131 patients (98.5%) in the intervention group and 118/125 patients (94.4%) in the conservative management group. Thus, the conservative management strategy yielded a success rate which was 4.1% lower than that of the intervention strategy, and the lower boundary of the 95% confidence interval was –8.6, which was within the non-inferiority margin. The same was true for the sensitivity analysis, when the 8-week follow-up was extended to 63 days (98.5% in the intervention group and 94.9% in the conservative group; difference –3.7%; 95% CI –7.9–0.6), but not when the missing data after 56 days were imputed as failure (93.5% in the intervention group and 82.5% in the conservative management group; difference –11%; 95% CI –18.4–3.5).

In the conservative strategy group, 15% of patients required some further intervention compared to 94% in the intervention strategy group, thus sparing 85% of the patients from an invasive procedure. This also translated into shorter hospital stay, prolonged intercostal tube drainage and need for surgery in the conservative approach group. Similarly, fewer patients in the conservative treatment group experienced any form of adverse or serious adverse events. In addition, the recurrence of pneumothorax over a 12-month period was 16.8% in the intervention group compared to 8.8% in the conservative group.

COMMENT

The first step in the management of spontaneous pneumothorax has been to classify whether it is primary (i.e. with an underlying healthy lung) or secondary (i.e. with an underlying diseased lung).[1] While secondary spontaneous pneumothorax usually calls for an intervention to drain out the air in the pleural cavity, the approach for the management of PSP could either be conservative or more aggressive, i.e. to drain out all the air. This depends primarily on two factors: the amount of pneumothorax and the clinical status of the patient.[2] Despite several years of research, the exact mechanism for the development of PSP is still unclear. The most popular theory is that air enters the pleural space through rupture of a small bleb.[3] However, it has also been postulated that the air enters the pleural cavity through a weakness in the visceral pleura.[4] It has been hypothesized that the visceral pleural site of leak will heal and thereby prevent further entry of air into the pleural space only when the lung is collapsed.[5] This implies that bringing the two pleural surfaces together by aggressively draining out the air will not facilitate healing. This probably is one of the reasons behind the conceptualization of the present study wherein the authors want to test the hypothesis of conservative non-intervention-based approach in the management of PSP allowing time for the visceral pleural leak to seal.

For clinicians managing PSP, an effective therapy would be one that leads to faster resolution of air in the pleural space and avoids future recurrences. The British Thoracic Society guidelines recommend an initial single time aspirate for pneumothorax measuring >2 cm, followed by small-bore intercostal drain in case of non-resolution.[2] However, it is essential to consider associated complications such as pain, bleeding and longer hospital stay that not only add to the discomfort but also to the overall cost of the procedure. If the air in the pleural space is left on its own, it is estimated that it will get reabsorbed at the rate of 1.25% every 24 hours.[6] This can be hastened by the addition of supplemental oxygen. Hence, as per the inclusion criteria in the present study, it would take a minimum of 2 weeks for complete resolution of the pneumothorax. As long as the patient is haemodynamically stable, with no pain and no signs of respiratory distress, this watchful observation is acceptable. The study has shown that almost 94% of patients in the conservative management group had complete resolution of pneumothorax within 8 weeks compared to 98% in the intervention group, though the median time for radiological resolution was longer in the conservative group (30 days *v.* 16 days). Another benefit was that the conservative strategy spared 85% of patients from an invasive intervention. An unexpected observation was that the recurrence rate of pneumothorax was 8% lower in the conservative group compared with the intervention group. This could possibly be due to gradual sealing of the visceral pleural leak in the conservative group; this sealing may have been prevented by the sudden apposition of the two pleural surfaces due to complete drainage of air in the intervention group.

Although the trial has shown that the conservative approach scores reasonably well in comparison to chest tube insertion, this may not be sufficient to generalize and recommend a conservative approach for all patients with PSP. The reasons being that first, this was a non-inferiority trial with an arbitrary assumption of the non-inferiority margin of –9%, and second, the non-availability of data (missing patients) for the primary analysis at 8-week follow-up period may have influenced the results. Around 40%–50% of patients in each group were current smokers. The risk of recurrence after an initial episode of PSP is estimated to be 30%–50%, and smoking significantly increases the risk.[7] It would have been interesting if a baseline CT scan was available to document the presence of blebs, bulla, etc., and a stratified randomization was done on the basis of such radiological and phenotypic characteristics.

In the Indian context, it is important for clinicians deciding to manage the first episode of PSP conservatively to ensure that the patient understands and recognizes the development of symptoms of respiratory distress when discharged from the hospital and promptly reports back. Similarly, if the patient does not have quick access to medical facilities in the vicinity, this management approach should be used with caution. Furthermore, such patients need to be educated to avoid activities such as heavy weightlifting, air travel and swimming, which may worsen the underlying pneumothorax.

To conclude, the feasibility of a conservative approach for the management of PSP should always be considered before more aggressive interventional approaches, since it can reduce the morbidity and cost of treatment. Similar well-conducted trials can help to make this strategy the standard of care.

Conflicts of interest. None declared

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